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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,180	11/23/2005	Carlos Alberto Genaro Mammarella	GBA-002	6486

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
01/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/526,180	MAMMARELLA, CARLOS ALBERTO GENARO	
	Examiner	Art Unit	
	GOLLAMUDI S. KISHORE	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 10-17* is/are pending in the application.

4a) Of the above claim(s) *10-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 9-28-09 is acknowledged.

Claims included in the prosecution are 1-5 and 17. Claims 10-16 remain withdrawn.

In view of the amendments to the claims, the 102 rejections are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Needham or WO 99 cited above.

Needham as discussed above discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed active agents (Fig. 4, 0040, 0043, 0048, 0072, 0085 and examples). The compositions further contain DSPE-PEG).

WO discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed active agents (Fig. 4, pages 7, 9, 13, 16 and examples). The compositions further contain DSPE-PEG (page 10).

Needham and WO however, do not specifically teach as to how much of doxorubicin is encapsulated. The amount of the active agent incorporated within the liposomes depends upon various parameters such as the method of loading and the nature of the lipids and its amounts and the severity of the disease and therefore, deemed to be an obvious parameter manipulatable by an artisan.

Applicant's arguments have been fully considered, but are not persuasive. Applicant draws the examiner's attention to Examples 4 and 8 of Needham (2002/012298) and argues that the procedure of loading in Example 4 is carried out by incubation at 60 degrees and the amount of doxorubicin entrapped is not disclosed. According to applicant, in Example 8 of Needham is carried out at 37 degrees achieving 80 % of doxorubicin loaded into the liposome which is considered "an improvement over the 30 or 40 % loading that occurs using conventional doxorubicin loading techniques, namely the temperature of 60 degrees". These arguments are not persuasive. First of all, Needham's statement itself implies and substantiates the examiner's position that one can manipulate the amounts of doxorubicin incorporated within the liposomes by varying the loading procedures. Secondly, as recognized by applicants themselves, Needham's procedure results in an entrapment of 80 % of doxorubicin and applicant indicates that the lower amount of doxorubicin entrapped in this invention is 87.9. Instant claims are product claims and as well known in the art, the active agents can be loaded using a pH gradient, ion gradients using ions such as ammonium ions. Therefore, it is within the skill of the art to manipulate the basic teachings of Needham and vary the experimental parameters to obtain increased encapsulation of doxorubicin.

The examiner does not see any unexpected results between instant amount and that that reported by Needham. Instant claims do not recite any specific saturated lipid or specific lyso phospholipid and applicants themselves have not shown that using any lipid combination one can obtain similar encapsulation.

3. Claims 3-5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Needham or WO cited above in combination with O'Brien (US 2002/0064554).

Needham as discussed above discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed active agents (Fig. 4, 0040, 0043, 0048, 0072, 0085 and examples). The compositions further contain DSPE-PEG). Needham however, does not specify whether the PEG-DSPE is a methylated PEG-DSPE.

WO discloses unilamellar liposomes of instant sizes containing the saturated lipid DPPC and the lyso lipid, DMPC in claimed molar amounts and claimed active agents (Fig. 4, pages 7, 9, 13, 16 and examples). The compositions further contain DSPE-PEG (page 10).

O'Brien while disclosing liposomal formulations teaches that either PEG or methyl PEG can be used to couple with phosphatidylethanolamine (0008). O'Brien's liposomes further contain cholesterol.

Assuming that PEG-DSPE taught by Needham or WO is not methylated PEG-DSPE, it would have been obvious to one of ordinary skill in the art to use methyl PEG to couple to PE with a reasonable expectation of success because of the equivalency taught by O'Brien.

Applicant's arguments have been fully considered, but are not persuasive. The examiner has already addressed applicant's arguments regarding Needham. Applicant provides no specific arguments with regard to O'Brien.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GOLLAMUDI S. KISHORE whose telephone number is (571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK